



Government  
of Canada      Gouvernement  
du Canada

**Risk Management Scope  
for  
Furan Compounds**

**Chemical Abstracts Service Registry Numbers  
(CAS RN):**

**98-00-0  
109-99-9**

Environment and Climate Change Canada

Health Canada

August, 2018

**Canada**

## **Summary of Proposed Risk Management**

This document outlines the risk management options under consideration for furan compounds, specifically:

- furfuryl alcohol (2-furanmethanol) CAS RN 98-00-0
- tetrahydrofuran (furan, tetrahydro-) CAS RN 109-99-9

In particular, the Government of Canada is considering:

1. Measures to help reduce consumer exposure to furfuryl alcohol from use of wood stripper products.
2. Measures to help reduce consumer exposure to tetrahydrofuran in polyvinyl chloride (PVC) solvent cements.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan (CMP) substances as required to ensure effective, coordinated, and consistent risk management decision-making.

**Note:** The above summary is an abridged list of options under consideration to manage this substance and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

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## 1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and the Minister of Health (the ministers) to conduct assessments to determine if substances are toxic to the environment and/or to human health as set out in section 64 of CEPA<sup>1,2</sup>, and if so to manage the associated risks.

The substances furan, Chemical Abstracts Service Registry Number (CAS RN)<sup>3</sup> 110-00-9, 1(3H)-isobenzofuranone, 3,3-bis(4-hydroxyphenyl); CAS RN 77-09-8, referred to in this document as phenolphthalein; 2-furanmethanol CAS RN 98-00-0, referred to throughout this document as furfuryl alcohol; and furan, tetrahydro- , CAS RN 109-99-9, referred to throughout this document as tetrahydrofuran, are included in the assessment of furan compounds, as part of the Chemicals Management Plan (CMP) (Canada 2018).

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<sup>1</sup> Section 64 [of CEPA]: *For the purposes of [Parts 5 and 6 of CEPA], except where the expression “inherently toxic” appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

- (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
- (b) constitute or may constitute a danger to the environment on which life depends; or*
- (c) constitute or may constitute a danger in Canada to human life or health.*

<sup>2</sup> A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

<sup>3</sup> CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

## 2. Issue

### 2.1 Draft Screening Assessment Conclusion

Health Canada and Environment and Climate Change Canada conducted a joint screening assessment of four substances referred to collectively as the Furan Compounds Group, specifically furan, phenolphthalein, furfuryl alcohol and tetrahydrofuran, to determine whether these substances present or may present a risk to the environment or to human health in Canada. A notice summarizing the scientific considerations of the risk assessment conclusions for these substances was published in the *Canada Gazette*, Part I, on September 1, 2018 (Canada 2018).

Based on the information available, the draft screening assessment proposes that furfuryl alcohol and tetrahydrofuran meet the criteria under paragraph 64(c) of CEPA as each of these substances are entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (Canada 2017). The draft screening assessment also proposes that furan and phenolphthalein do not meet the criteria under paragraph 64(c) of CEPA.

The draft screening assessment also proposes that furan, phenolphthalein, furfuryl alcohol, and tetrahydrofuran are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends under section 64(a) or 64(b) of CEPA, respectively (Canada 2017).

The exposures and sources of concern identified in the draft screening assessment are inhalation exposure from furfuryl alcohol in wood strippers, and inhalation exposure from tetrahydrofuran in PVC solvent cements (refer to section 5). The assessment also noted concern for human health if exposures to phenolphthalein were to increase, so follow up activities to track changes in exposure or commercial use patterns are also under consideration.

Of note, the proposed risk management options described in this document and the proposed conclusion outlined in the draft screening assessment may be subject to change. For further information on the draft screening assessment for the Furan Compounds, refer to the [Furan Compounds Group](#).

## **Proposed Recommendation Under CEPA**

Based on the findings of the draft screening assessment conducted under CEPA, the ministers propose to recommend that furfuryl alcohol and tetrahydrofuran be added to the List of Toxic Substances in Schedule 1 of the Act<sup>4</sup>.

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft Screening Assessment and Risk Management Scope documents in the preparation of the final screening assessment and Risk Management Approach document, if required. If furfuryl alcohol and tetrahydrofuran are concluded to meet one or more of the criteria under section 64 of CEPA at the time of the final screening assessment and the ministers finalize the recommendation to add these substances to Schedule 1, risk management instrument(s) will be proposed within 24 months from the date on which the final screening assessment is published, and finalized within 18 months from the date on which the risk management instrument(s) are proposed.

### **3. Proposed Risk Management**

#### **3.1 Proposed Human Health Objectives**

Proposed human health objectives are quantitative or qualitative statements of what should be achieved to address human health concerns.

For furfuryl alcohol, and tetrahydrofuran, the proposed human health objectives are focused on addressing the exposure sources of concern outlined in section 5 of this document. As such, the proposed human health objective is to reduce exposure of the general population to furfuryl alcohol and tetrahydrofuran to levels that are protective of human health.

#### **3.2 Proposed Risk Management Objectives and Options under Consideration**

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objectives for these substances for the protection of human health are:

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<sup>4</sup> When a substance is found to meet one or more of the criteria under section 64 of CEPA, the ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

- (1) to reduce inhalation exposure to furfuryl alcohol from wood strippers and;
- (2) to reduce inhalation exposure to tetrahydrofuran from PVC solvent cements.

To achieve the proposed risk management objectives and to work towards achieving the proposed human health objective, the risk management options under consideration are:

- (1) Measures to help reduce consumer exposure to furfuryl alcohol in wood stripper products through the implementation of regulatory and/or non-regulatory controls. These could include voluntary actions by industry via mechanisms such as Memoranda of Understanding (MOUs), Environmental Performance Agreements (EPAs), or codes of practice, or regulatory actions under the *Canadian Environmental Protection Act 1999* (CEPA).
- (2) Measures to help reduce consumer exposure to tetrahydrofuran in PVC solvent cements through the implementation of regulatory and/or non-regulatory controls. These could include voluntary actions by industry via mechanisms such as MOUs, EPAs, or codes of practice, or regulatory actions under CEPA 1999.

Following the publication of this Risk Management Scope document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process<sup>5</sup>. The risk management options outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

### **3.3 Risk Management Information Gaps**

In order to make informed decisions on proposed risk management, information on possible alternative substances to replace tetrahydrofuran in PVC solvent cements is requested.

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<sup>5</sup> The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulatory Management (TBS 2012a), Red Tape Reduction Action Plan (TBS 2012b) and the *Red Tape Reduction Act* (Canada 2015).

## 4. Background

### 4.1 General Information on Furfuryl Alcohol and Tetrahydrofuran

Furfuryl alcohol and tetrahydofuran are organic substances within the Furan Compounds Group which also includes furan and phenolphthalein, which were grouped together on a structural basis, although due to the significant differences in use patterns and health effects, they were considered individually in the human health portion of the assessment. In addition, substance-specific profiles for all four substances in the Furan Compounds Group were developed for environmental evaluation of these substances under this initiative (Canada 2018).

### 4.2 Current Uses and Identified Sectors

#### 4.2.1 Furfuryl alcohol

Furfuryl alcohol was included in surveys issued pursuant to section 71 of CEPA (Canada 2012). No manufacture in Canada was reported, although imports of furfuryl alcohol in the range of 100,000 -1,000,000, were reported in 2011 (Environment Canada 2013).

Canadian sectoral uses reported in response to the survey include automotive, aircraft and transportation, building or construction material, metal materials, paints and coatings, and plastic and rubber materials (Environment Canada 2013).

Globally, furfuryl alcohol is reportedly used in paints and coatings, as a solvent in cleaning and paint-removal, as an intermediate in the manufacture of resins and plastics, and as a viscosity reducer for epoxy resins (HSDB 1983b, ECHAc 2007-2016b). However, in Canada, while the use of furfuryl alcohol in wood stripper products available to the general population has been confirmed (MSDS 2016), it has also been verified that furfuryl alcohol is not present in epoxy products marketed for the general population in Canada (personal communication 15/03/07).

Furfuryl alcohol is naturally occurring in a wide range of foods including coffee, roasted nuts and grains, alcoholic beverages, fruits, vegetables, meats, and dairy products (Burdock 2010, HSDB 1983a; 1983b; 1983c; 1983d). In addition, furfuryl alcohol may be used as a food flavouring. The Food Chemicals Codex (FCC) indicates that furfuryl alcohol has the function of a flavouring agent (FCC USP 2016). It is listed in Fenaroli's Handbook of Flavor Ingredients (Burdock 2010). The European Union permits furfuryl alcohol to be used as a flavouring in

food (EU Food Flavourings Database). No definitive information is available concerning the potential use of furfuryl alcohol as a food flavouring in Canada (personal communication, emails from Food Directorate to Existing Substances Risk Assessment Bureau, dated December 2016; unreferenced).

#### **4.2.2 Tetrahydrofuran**

Tetrahydrofuran was included in surveys issued pursuant to section 71 of CEPA (Canada 2012). This substance was not reported to be manufactured in Canada, although imports of 384,594 kg tetrahydrofuran were reported in 2011 (Environment Canada 2013).

Canadian sectoral uses for tetrahydrofuran reported in response to the survey include adhesives and sealants, automotive, aircraft and transportation, building or construction material, paints and coatings, pharmaceutical manufacturing, plastic and rubber materials and solvents (Environment Canada 2013).

Globally, tetrahydrofuran is used mainly as a solvent in the production of resins and plastics, particularly polytetramethylene ether glycol (PTMEG), as well as in the manufacture of paints and coatings, paint and varnish removers, and adhesives such as PVC cement. There are also some reports of use in cleaning products (furniture polish and cleaners, laundry starch preparations and stain removers). However, no evidence of the consumer applications noted above uses was identified in Canada (HSDB 1983c, OECD 2000, ECHA c2007-2016c), except for the presence of tetrahydrofuran in PVC cement products available to the general population in Canada (MSDS 2013; MSDS 2014).

Unlike certain other furan compounds, tetrahydrofuran does not occur naturally in the environment.

### **5. Exposure Sources, Effects and Identified Risks**

#### **5.1 Furfuryl Alcohol**

A critical health effect associated with furfuryl alcohol identified in the draft screening assessment (Canada 2018) is carcinogenicity. Critical non-cancer endpoints associated with exposure to furfuryl alcohol include decreased breathing rate and decreased body weight gain.

The critical focus of the latter evaluation is decreased breathing rate associated with acute inhalation exposure to furfuryl alcohol of Canadian consumers, during use of wood strippers, the only consumer use identified in Canada. Estimated inhalation exposure from product use was compared to the critical inhalation effect levels to derive margins of exposure (MOEs) for determination of risk.

These MOEs are considered potentially inadequate to account for the protection of human health.

Exposures to furfuryl alcohol from environmental media or food in Canada were not considered to pose a risk to human health.

## **5.2 Tetrahydrofuran**

A critical effect associated with tetrahydrofuran identified in the draft screening assessment is carcinogenicity, although it has been proposed that tumours likely arise through non-genotoxic pathways (Canada 2018). Critical non-cancer endpoints associated with exposure to tetrahydrofuran are central nervous system (CNS) toxicity, increased liver weight and cytomegaly, and developmental toxicity.

The critical focus of the latter evaluation is CNS toxicity associated with acute inhalation exposure to tetrahydrofuran of Canadian consumers during use of PVC pipe cement, the only consumer use identified in Canada. Estimated inhalation exposure from product use was compared to the critical inhalation effect levels to derive margins of exposure (MOEs) for determination of risk. These MOEs are considered potentially inadequate for the protection of human health. In addition, some products require the use of a primer before the PVC cement is applied. These products may also contain tetrahydrofuran, thereby increasing the potential exposure.

However in the evaluation, exposure through inhalation to tetrahydrofuran in indoor air concentrations by the general Canadian population, is considered to be adequate for the protection of human health.

# **6. Risk Management Considerations**

## **6.1 Alternatives and Alternate Technologies**

With respect to wood strippers containing furfuryl alcohol, there is a wide variety of wood stripper products available on the market which do not contain furfuryl alcohol. Therefore there are readily-available alternatives to this product.

Nearly all PVC solvent cements on the market contain tetrahydrofuran, although at varying concentrations. Information on possible alternative substances for tetrahydrofuran in PVC cement products has also been identified, those being

methyl ethyl ketone and N-methyl-2-pyrrolidone (NMP). Both are currently subject to assessment under Canada's Chemicals Management Plan.

## **6.2 Socio-economic and Technical Considerations**

Socio-economic factors will be considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objectives(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Regulatory Management* (TBS 2012a) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (TBS 2007).

# **7. Overview of Existing Risk Management**

## **7.1 Related Canadian Risk Management Context**

Domestically, the following risk management actions are as follows:

### **7.1.1 Furfuryl Alcohol**

*Transportation of Dangerous Goods Regulations*, Schedule1, under the *Transportation of Dangerous Goods Act* – This schedule lists the safety specifications for transport of this substance and other dangerous goods by land or water.

### **7.1.2 Tetrahydrofuran**

*Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* under the *Canadian Environmental Protection Act 1999* (CEPA ) - SOR/2005-149 (Schedule 7) - *The Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* (the Regulations) made pursuant to CEPA, apply to movements of hazardous wastes and hazardous recyclable materials crossing an international border when destined for disposal or recovery. Therefore, if a waste or recyclable material is exported, imported or conveyed in transit through Canada to be disposed of using one of the operations set out in Schedule 1 of the Regulations, or to be recycled using one of the operations set out in Schedule 2 of the Regulations and it is defined or considered 'hazardous' under section 1, 1.1, 2 or 2.1 of the Regulations, then the Regulations would apply. Tetrahydrofuran is listed under Schedule 7 of the Regulations and is classified as a hazardous material. Therefore the Regulations may apply as described above.

The Regulations and CEPA require hazardous waste and hazardous recyclable material transported across international borders to be managed appropriately to protect the environment and human health.

Natural Health Products (NHP) - With respect to the requirements in place for the quality of NHPs, tetrahydrofuran is listed as a Class 2 residual solvent in the USP 467 Residual Solvents general chapter, with a concentration limit of 720 ppm and a permitted daily exposure (PDE) of 7.2 mg/day. As such, the expectation would be that this PDE be respected for NHPs that have used this solvent in the manufacturing of the finished product and/or its ingredient(s).

Foods and Food Packaging - Tetrahydrofuran is not on the Lists of Permitted Food Additives in Canada; therefore it is not permitted to be used as a food additive in Canada at this time. Tetrahydrofuran can be formed as an impurity during the manufacture of some resins used in food packaging materials with direct food contact, including films, coatings or molded articles. It has also been identified as a component in cleaners for possible use in food processing establishments but for this type of use there would be no direct contact with food. There is no pre-market review/approval process for food packaging materials, or incidental additives used in food processing facilities at this time. However, packaging materials in which food is sold must comply with safety provisions set out under Division 23 of the Canadian *Food and Drug Regulations* (FDR). Division 23 prohibits the sale of foods in packages that may impart to the food any substance that may be injurious to human health. The responsibility to meet this requirement rests with the food seller. The safety of chemicals in food packaging materials, and in incidental additives are also subject to section 4 of the *Food and Drugs Act* (F&DA), which states that no person shall sell an article of food that has in or on it any poisonous or harmful substance. Again, the onus to meet this requirement rests with the food seller.

## **7.2 Pertinent International Risk Management Context**

Internationally, the following pertinent risk management actions are as follows:

### **7.2.1 Furfuryl Alcohol**

#### **United States**

None.

#### **European Union**

None.

### **Other**

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) determined that there were no safety concerns at current levels of intake when furfuryl alcohol is used as a flavouring agent. A group Acceptable Daily Intake (ADI) of 0-0.5 mg/kg bw was also established (WHO, 2001)

### **7.2.2 Tetrahydrofuran**

#### **United States**

U.S. EPA TSCA (*Toxic Substance Control Act*): Tetrahydrofuran is listed on the TSCA inventory, a list of each chemical substance that is manufactured or processed, including imports, in the U.S.; in addition, exporters are required to notify the U.S. EPA of their intention to export this substance, and the U.S. EPA, in turn, provides information about the substance and its related regulatory actions, to the importing government.

U.S. Code of Federal Regulations, Title 21, Volume 3, April 2016, 21CFR178.3950, Food and Drugs - tetrahydrofuran may be safely used in the fabrication of articles intended for packaging, transporting, or storing foods when used as a solvent in the casting of film for food contact applications at a concentration not exceeding 1.5 percent by weight of film.

#### **European Union**

Commission Directive 2007/42/EC (June 2007) relating to materials and articles made of coated regenerated cellulose film intended to come into contact with foodstuffs, which permits the use of tetrahydrofuran as a solvent. The total quantity of this substance may not exceed 0.6 mg/dm<sup>2</sup> (6%) of the coating on the side of the cellulose film which is in contact with foodstuffs.

*Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures* - List of harmonised classification and labelling of hazardous substances, which specifies tetrahydrofuran as a carcinogen and respiratory and eye irritant and appropriate labelling requirements.

### **Other**

None.

## 8. Next Steps

### 8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Scope or other information that would help to inform decision-making (such as outlined in sections 3.2). Please submit additional information and comments prior to October 31, 2018. The Risk Management Approach document, which will outline and seek input on the proposed risk management instrument(s), will be published at the same time as the final screening assessment. At that time, there will be further opportunity for consultation.

Comments and information submissions on the Risk Management Scope should be submitted to the address provided below:

Environment and Climate Change Canada  
Chemicals Management Division  
Gatineau, Québec K1A 0H3  
Tel: 1-800-567-1999 | 819-938-3232  
Fax: 819-938-5212  
Email: [eccc.substances.eccc@canada.ca](mailto:eccc.substances.eccc@canada.ca)

Companies who have a business interest in furfuryl alcohol or tetrahydofuran are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding furfuryl alcohol and tetrahydofuran and may be contacted for further information.

## 8.2 Timing of Actions

Action	Date
Electronic consultation on the Risk Management Scope	September 1, 2018 to October 31, 2018
Submission of additional studies or information on furfuryl alcohol and tetrahydrofuran	on or before October 31, 2018
Publication of responses to public comments on the draft screening assessment and Risk Management Scope	No later than the time of publication of the final screening assessment
Publication of the final screening assessment and, if required, the Risk Management Approach document	2020
Publication of responses to public comments on the Risk Management Approach, if applicable, and publication if required, of the proposed instrument(s)	At the latest, 24-months from the publication of the final Screening Assessment Report
Consultation on the proposed instrument(s), if required	60-day public comment period starting upon publication of each proposed instrument
Publication of the final instrument(s), if required	At the latest, 18 months from the publication of each proposed instrument

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